MAY - 2 2001

K010305

510(K)SUMMARY

Submitter's Name: Micron Surgical, Inc.

Address: 5800 Colonial Dr., Suite 300
Margate, FL 33063

Telephone #: (415) 464-0123

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Official Correspondent: April K. Dean

Registration Number: None at this time

Date Summary Prepared: 23 January, 2001

Device Name:

Classification Name: Ophthalmic Cannula

Proprietary Name: Weiss Retinal Cannula

Common Name: Disposable Ophthalmic Cannula

Class: 1

Panel: Ophthalmic

Product Code: HMX

Device Description:

The Weiss Retinal Cannula is a disposable ophthalmic cannula that is appropriately sized in length and diameter to allow its introduction through an incision in the eye, and to provide for use of the needle for the infusion of a selected material into the subretinal space, intraretinal space, or intravascular retinal space.

The cannula assembly is comprised of a stainless steel blunt end hypodermic needle affixed by luer lock to a cylindrical handle; an appropriate length of polymeric tubing, radially sized such that it will fit and slide over the stainless steel tube; a microneedle fabricated from borosilicate glass tubing, the diameter of which fits within the stainless steel tube and is affixed at the back end of the tube; a barb fitting threaded into the back of the handle to accept polyethylene tubing.

The proximal end of the microneedle protrudes 3mm from the proximal end of the hypo tube. The outside tip diameter of the microneedle is nominally 70 microns and the inside diameter nominally 50

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microns. The tip is beveled at 30 degrees. A bend is applied to the microneedle shank distal from the tip.

The stainless hypo tube and the polymeric tube serve as protective sleeves for the borosilicate glass. The stainless steel hypo tube protects the shaft of the glass tube and the polymeric tube serves as an over-sheath for protection of the needle tip when being introduced or withdrawn from the eye.

In use, the entire assembly is manually advanced into the vitreous cavity through a sclerotomy. Once inserted into the vitreous cavity, the polymeric tube is retracted to expose the microneedle tip. Under microscopic visualization, the needle tip is advanced into a retinal vessel. The desired material is then injected through the cannula and into the retinal vessel. When the infusion is complete, the cannula is removed from the vessel, the sleeve is advanced proximally to extend beyond the microneedle tip and the entire assembly withdrawn from the eye. The assembly is sized in overall length to best facilitate this procedure. The cannula is provided sterile and intended for use on a single patient only.

To date, 65 surgeries in humans have been performed utilizing prototype cannulae for infusing the central retinal vein. Other uses have included: 1) Flushing saline into the subretinal space to dilute hemorrhages as well as to elevate the retina to aid in extracting subretinal membranes, and 2) Incising the sheath between the retinal arteriole and venule for branch retinal vein occlusion.

Statement of indications for use:

The Weiss Retinal Cannula is used for microinjection into the subretinal space, intraretinal space or intravascular retinal space.

Substantial Equivalence Comparison:

Comparative Device	Weiss Retinal Cannula	Synergetics- 42ga Rigid Micro Injection Cannula	Humagen-Microtools
Indications for use	Used in performance of injections into the sub, intra, or intravascular retinal space.	Micron-infusion of non-viscous liquids for hydro-dissection of the retina	For use in assisted reproduction embryo injection procedures
Needle Tip Outer Diameter	70 microns	150 microns	10-200 microns
Needle Material	Borosilicate Glass-Pyrex (Corning 7740)	Polyimide Coated Fused Silica	Borosilicate Glass-(Kimble N51-A)
Outer Sleeve	304 Stainless steel	Stainless Steel	N/A
Protective Over-sheath	Polyester tubing	N/A	N/A
Back end connection	Nylon barb fitting	Nylon luer fitting	N/A
Packaging	Polystyrene box in Heat Sealed Tyvek Pouch	Polystyrene tube in Heat Sealed Tyvek Pouch	Polystyrene tube in Heat Sealed Tyvek Pouch
Sterilization	ETO	ETO	Gamma radiation

Sterility:

Sterilization will be performed with Ethylene Oxide. The sterilization validation program will follow ANSI/AAMI/ISO 11135-1994 procedures.

A Sterility Assurance Level of 10^{-6} or greater will be achieved by the sterilization cycle employed. Residuals will be in compliance with ISO 10993-7.

Each lot of cannulae will be tested for endotoxin levels using the Limulus Amebocyte Lysate assay. The level of endotoxin units per device must be less than 20 to be considered acceptable.

Cannulae are packaged individually.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. April Dean
Micron Surgical
5800 Colonial Dr., Suite 300
Margate, FL 33063

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Re: K010305
Trade Name: Weiss Retinal Cannula
Regulatory Class: I
Product Code: 86 HMX
Regulation: 886.4350
Dated: January 30, 2001
Received: February 1, 2001

Dear Ms. Dean:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K010305

Device Name: WEISS RETINAL CANNULA

Indications For Use: THE PRIMARY INDICATION FOR THIS DEVICE IS THE MICROINJECTION OF FLUID INTO THE SUBRETINAL SPACE, INTRARETINAL SPACE OR INTRAVASCULAR RETINAL SPACE.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010305

(Optional Format 3-10-98)